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TORT REFORM—WHAT ABOUT THE LITTLE GUY?

*Dawn House**

I. INTRODUCTION¹

The massive recall of defective medical heart devices² raises the question of how effectively the U.S. Food and Drug Administration (FDA) regulates the industry that manufactures heart devices implanted in the chests of tens of thousands of people.³ The issue has become political as Congress passes tort reform legislation designed to limit people's ability to go to court seeking redress. Missing in the debate are the people whose lives depend on medical heart devices.⁴ Their voices and experiences continually have gone unheard.

A primary example of how the FDA fails patients is in the case of Guidant Corporation ("Guidant"), one of the nation's three largest heart device manufacturers.⁵ Executives reportedly knew for those

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1. I stepped into a different world when I had the privilege of monitoring a panel at Loyola Law School's symposium, *Access to Justice: The Economics of Civil Justice*. I am a reporter for *The Salt Lake Tribune* and, more to the point, I do not think or write like an academic. I believe in the power of the narrative, of stories about people whose lives are changed or harmed by dominant forces, particularly business or government interests, which are much greater than themselves.

2. See *infra* notes, 3, 28, 31 and 160.

3. See Lauran Neergaard, *FDA: Defibrillator Defects on the Rise*, DETROIT NEWS, Sept. 17, 2005, <http://www.detnews.com/2005/health/0509/18/health-317834.htm>. These malfunctioning devices include pacemakers, which regulate irregular heartbeats, and defibrillators, which send an electrical charge to the heart to interrupt a potentially fatal rhythm. *Id.*

4. See *infra* Part I.

5. Barry Meier, *F.D.A. Had Report of Short Circuit in Heart Devices*,

three years about flaws in one of its widely used defibrillators⁶ but the company did not tell physicians about the problems until May 2005.⁷ Months earlier, Guidant informed the FDA that the company's product, Ventak Prizm 2 DR, was short circuiting approximately once a month.⁸ The FDA, however, did not notify the public of this problem until June 2005.⁹ The public notification came several months after a college student, who had one of the defibrillators implanted in his chest, died when the device reportedly failed.¹⁰

Against this backdrop, the Republican-controlled Congress has passed legislation limiting people's access to the courts and is considering more tort-reform bills.¹¹ The FDA meanwhile announced that it would renew efforts to more closely regulate the medical heart device industry,¹² and companies have announced that they will rekindle their goal of protecting customers.¹³ These announcements apparently have satisfied Congress, which has no pending bills affecting either medical heart devices or their manufacturers.¹⁴

The nonpartisan Center for Responsive Politics, which tracks

N.Y. TIMES, Sept. 12, 2005, at A1.

6. *Id.*

7. *Id.*; see also Press Release, Guidant, Guidant Notifies Physicians Regarding VENTAK 1861 PRIZM 2 DR Implantable Defibrillator (May 25, 2005), http://www.guidant.com/news/500/web_release/nr_000546.shtml.

8. Meier, *supra* note 5, at A1.

9. *Id.*

10. *Id.*

11. See, e.g., Class Action Fairness Act of 2005, Pub. L. No. 109-2, 119 Stat. 4 (codified in scattered sections of 28 U.S.C.).

12. See Press Release, FDA, FDA Announces New Program to Transform and Strengthen Medical Device Safety (Jan. 20, 2006), <http://www.fda.gov/bbs/topics/news/2006/NEW01300.html>.

13. See, e.g., Press Release, Guidant, Guidant Response to Media Story on Product Performance (Oct. 20, 2005), http://www.guidant.com/news/500/web_release/nr_000585.shtml; Press Release, Guidant, Guidant Publishes Responses to U.S. Food and Drug Administration Form 483 Observations (Oct. 27, 2005), http://www.guidant.com/news/500/web_release/nr_000587.shtml.

14. See generally Library of Congress, Bills, Resolutions—Thomas, http://thomas.loc.gov/home/bills_res.html (last visited Feb. 14, 2006) (allowing the public to search for pending congressional bills; no bills of this type pending as of date of publication).

money in politics,¹⁵ reports that Republicans and their business supporters have consistently tried to change “the rules on class-action lawsuits, only to be thwarted in their efforts by consumer groups and trial lawyers.”¹⁶ After the 2004 elections, however, the Republican-controlled Senate began debating the Class Action Fairness Act (CAFA),¹⁷ which grants federal jurisdiction to class action lawsuits, a forum considered more favorable to corporate clients.¹⁸

The Senate passed the bill in February 2005 by a vote of 72 to 26,¹⁹ rejecting Democratic amendments that would have made it more difficult for federal courts to dismiss class action claims.²⁰ The House passed the measure by a vote of 279 to 149 the following week.²¹ President George W. Bush signed the bill into law on February 18, 2005.²² It was a huge victory for business associations, which sent eighty-four percent of their individual and Political Action Committee (PAC) contributions to Republicans²³ and spent tens of millions of dollars on lobbying in the 2004 elections.²⁴ It also was a big win for the U.S. Chamber of Commerce, which was the leading business group lobbying in favor of class action and tort reform, and raises millions in corporate contributions for its legislative efforts.²⁵ In 2003, more than \$16 million of those contributions went toward lobbying the federal government.²⁶

CAFA, passed by Congress and signed into law within eight

15. Center for Responsive Politics, About the Center for Responsive Politics, <http://www.opensecrets.org/about/index.asp> (last visited Jan. 31, 2006).

16. Ctr. for Responsive Politics, Courts: Class Action Reform, <http://www.opensecrets.org/payback/issue.asp?issueid=CA1&CongNo=109> (last visited Jan. 31, 2006).

17. Class Action Fairness Act of 2005, Pub. L. No. 109-2, 119 Stat. 4 (codified in scattered sections of 28 U.S.C.). See Center for Responsive Politics, *supra* note 16.

18. See GEORGENE M. VAIRO, THE CLASS ACTION FAIRNESS ACT OF 2005: A REVIEW AND PRELIMINARY ANALYSIS (2005).

19. 151 CONG. REC. S1225, S1249 (2005).

20. Center for Responsive Politics, *supra* note 16.

21. 151 CONG. REC. H723, H755 (2005).

22. See Class Action Fairness Act of 2005, 119 Stat. 4.

23. Center for Responsive Politics, *supra* note 16.

24. *Id.*

25. *Id.*

26. *Id.*

days, marked a major defeat for the Association of Trial Lawyers of America (ATLA) because the Act limits a plaintiff's opportunity to bring a case to court.²⁷

Consumers have filed dozens of class-action lawsuits against Guidant since the company's recall of 109,000 defibrillators.²⁸ On November 7, 2005, a federal multidistrict litigation panel consolidated cases before one federal judge in Minnesota,²⁹ where one of Guidant's Cardiac Rhythm Management Division is located.³⁰

Guidant is not the only company that has recalled medical devices. In February 2005, the largest heart device manufacturer, Medtronic Inc., advised physicians about potential battery failures in 87,000 of some of its implantable-model defibrillators.³¹ Within a mere four months, St. Jude Medical Inc. announced that 30,000 of its defibrillators needed software upgrades to prevent potential problems.³²

The issue surrounding defective heart devices is particularly urgent because the number of people with implantable cardioverter defibrillators (ICD) is increasing.³³ The federally funded Center for Medicare and Medicaid Services paid for 52,500 defibrillator implantations in 2003 and for 65,000 the next year.³⁴ These federally funded programs are also paying for replacement surgeries and, because manufacturers' warranties only cover their own models, these additional costs are falling on taxpayers' shoulders.

Heart devices, which are widely used to treat cardiovascular disease, have become a life-or-death issue for many Americans. Cardiovascular disease is the number one killer in the United States,

27. *Id.*

28. Avram Goldstein, *Guidant Lawsuit Settlement May Be First Tied to Defibrillators*, BLOOMBERG.COM, Nov. 22, 2005, http://quote.bloomberg.com/apps/news?pid=10000103&sid=aLvCq8w8Si9I&refer=news_index.

29. *Id.*

30. Guidant, About Us, Locations, <http://www.guidant.com/about/locations.shtml> (last visited Jan. 31, 2006).

31. Robert Steinbrook, *The Controversy over Guidant's Implantable Defibrillators*, 353 NEW ENG. J. MED. 221, 223 (2005).

32. *Id.*

33. E-mail from Zina Lewis to Dawn House, Reporter, The Salt Lake Tribune (Feb. 21, 2006, 15:37:00 MST) (on file with author) (stating that "[i]n 2004, an estimated 135,000 devices were implanted in patients in the United States alone, a near tripling of the number in 2000").

34. Steinbrook, *supra* note 31, at 222.

claiming more lives than the next four leading causes of death combined.³⁵ To put it another way, the number of Americans under the age of sixty-five who die from heart disease each year is over 150,000³⁶—which, coincidentally, is about half the number of pacemakers and defibrillators taken off the market this year alone.³⁷ This combination of increased heart disease and faulty treatment therein is, put simply, lethal.

II. MEDICAL EXPERTISE DOES NOT MITIGATE DANGERS

Despite this problem of epidemic proportions, the congressional debate over tort reform largely lacked input from those very people who might die from heart device failure. Zina Lewis, age thirty-eight, of Salt Lake City, is one of the few people actually telling her story and trying to bring about change.³⁸

Lewis grew up in the University of Utah hospital after contracting a severe case of viral pneumonia when she was fourteen-years-old.³⁹ By the time she was nineteen, after years of worsening heart problems, she underwent a medical procedure that created a complete atrioventricular block, making her one hundred percent dependent on a pacemaker.⁴⁰

Although she had to complete some of her university course work from a hospital bed, she was grateful to be essentially symptom

35. AM. HEART ASS'N, HEART DISEASE AND STROKE STATISTICS—2005 UPDATE 3 (2005), <http://www.americanheart.org/downloadable/heart/1136308648540Statupdate2006.pdf> (naming the next four leading causes of death as “cancer, chronic lower respiratory diseases, accidents, and diabetes mellitus”).

36. *Id.*

37. Neergaard, *supra* note 3 (stating that of the numerous pacemakers and defibrillators doctors implanted from 1990 to 2002, more than 17,000 of them had to be surgically removed because of malfunctions).

38. ZINA LEWIS, STATEMENT TO THE HEART RHYTHM SOCIETY AND THE HEART RHYTHM FOUNDATION IN COOPERATION WITH THE FOOD AND DRUG ADMINISTRATION (FDA): RE: PROTECTING LIFE, PRESERVING TRUST AND PROMOTING HEALTH: A PATIENT'S VOICE FOR SAFETY 2 (2005), *available at* http://www.edfirmage.net/HRS_Statement1.pdf (abstract prepared for the Policy Conference on Pacemaker and ICD Performance).

39. *Id.*

40. *Id.* at 2, 6; DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 228 (30th ed. 2003) (defining an atrioventricular block as an “impairment of conduction of cardiac impulses from the atria to the ventricles”).

free.⁴¹ She held this belief until December 1992 when she learned that the lead wire for her pacemaker had been taken off the market nearly a year and a half before.⁴² It was against the law for manufacturers to directly notify patients when heart devices are found to be defective.⁴³ Instead, companies contacted physicians who, in turn, informed patients “regardless of whether or not the patient was currently under their care.”⁴⁴ Lewis’ home address, tucked away in her physician’s file cabinet in Utah, had been incorrectly recorded.⁴⁵ Lewis finally learned about the defective Medtronic lead wire during a routine checkup at the Coronary Care Unit at University of Utah Hospital.⁴⁶

Although the FDA was aware of certain medical device recalls, they failed to relay that information to Lewis.⁴⁷ This failure could be attributed to the FDA’s reliance on heart-device manufacturers for most if its data in deciding when to recall devices.⁴⁸

Her story is all the more troubling because Lewis is an advanced practice nurse and the Manager of Clinical Research and Development at an institution that participated in clinical trials sponsored by industry companies, including Guidant.⁴⁹ Despite her medical background, Lewis did not know for nearly one and a half years about the recall on her pacemaker’s lead wires,⁵⁰ which are wires that carry electrical impulses from the pacemaker to the heart.⁵¹ Her trust in both the FDA and device manufacturers has consequently declined.⁵²

41. See Dawn House, *Utah Woman Wants Answers About her Pacemaker*, SALT LAKE TRIB., Nov. 6, 2005, at E7.

42. LEWIS, *supra* note 38, at 6.

43. *Id.*

44. *Id.*

45. See *id.*

46. *Id.*

47. See *id.* at 15.

48. See *id.* at 24; see, e.g., Meier, *supra* note 5 (stating that the FDA learned of the *Prizm 2 DR* defect through Guidant’s annual report submitted to the organization).

49. LEWIS, *supra* note 38, at 2.

50. *Id.* at 6.

51. See Yale Medical Group, Cardiovascular Diseases: Overview of Pacemakers/Defibrillators, <http://ymghealthinfo.org/content.asp?pageid=P00234> (last visited Feb. 16, 2006).

52. See LEWIS, *supra* note 39, at 2 (“Though I have sustained life altering, and in all likelihood, life-shortening . . . injury due to device therapy over the

Lewis already has endured three operations to replace faulty lead wires;⁵³ one operation injured her heart even more, leaving a damaged and torn tricuspid valve and a hole between an artery and vein.⁵⁴ In 2002, her pacemaker was replaced with Guidant Pulsar Max II,⁵⁵ and a year later, that device was recalled as well.⁵⁶ Even before that recall, Lewis experienced rapid deterioration related to pacing and tachycardia issues, which eventually led to Lewis' heart failure.⁵⁷ She underwent numerous treatments and open-heart surgery to replace the pacemaker, both lead wires, and a heart valve.⁵⁸

In September 2005, her Guidant pacemaker, Insignia, also was recalled.⁵⁹ Given her dependence on her pacemaker and her underlying heart disorder, another surgery was scheduled in November, 2005, a month after the recall.⁶⁰

Lewis considered this failure to inform "a decision which jeopardized [her] life."⁶¹ And she understands the consequences of delayed notification because of her expertise in the medical field.⁶²

Yet even with their medical backgrounds,⁶³ Lewis and her husband have been unable to advocate change in the federal reporting system, such as requiring physicians, the FDA and manufacturers to notify patients when devices are recalled.⁶⁴ This change in policy makes sense because both the FDA and the companies maintain registries with patients' names.⁶⁵ Cardiologist

years, I have trusted the device manufacturers and the FDA as 'partners for life,' until now.'").

53. *See id.* at 2, 8, 10.

54. *Id.* at 6–8.

55. *Id.* at 11.

56. *Id.* at 15.

57. *See id.*

58. *Id.* at 6–16; *see also* House, *supra* note 41, at E7.

59. Press Release, Guidant, Guidant Initiates Voluntary Physician Advisory on Certain Pacemakers (Sept. 22, 2005), http://www.guidant.com/news/500/web_release/nr_000576.shtml.

60. *See* House, *supra* note 41.

61. LEWIS, *supra* note 38, at 6.

62. *See id.* at 2. Lewis had an eighteen-year career in cardiovascular medicine at the University of Utah Medical Center and a large biotechnology firm. *Id.*

63. E-mail from Zina Lewis to Dawn House, *supra* note 34.

64. *Id.*

65. *See* LEWIS, *supra* note 38, at 29.

Roger Freedman, a heart-device specialist at the University of Utah and consultant for Guidant, Medtronic and St. Jude, agrees that the reporting system needs a back-up.⁶⁶ Freedman explained that “[i]t would be a huge administrative burden so some type of financial support would be necessary, but we must be able to get unbiased, up-to-date information on the reliability of these devices.”⁶⁷

New York Attorney General Eliot Spitzer filed a civil lawsuit in November, 2005 against Guidant in the New York State Supreme Court, claiming Guidant hid information on defects with its defibrillators (specifically the Prizm 2 DR Model 1861) that could cause the device to fail with potentially fatal consequences.⁶⁸ Spitzer called Guidant’s behavior fraudulent⁶⁹ and further stated that “[w]e wouldn’t permit this type of conduct in connection with the sale of cars or washing machines. It is simply unconscionable that it occurred with a critical medical device.”⁷⁰

The lawsuit makes a claim under section 63(12) of the state’s Executive Law,⁷¹ which empowers the Attorney General’s Office to sue individuals or entities that engage in repeated or persistent fraudulent or illegal business practices.⁷² By definition, the term fraud, in its general sense, includes concealment.⁷³ The complaint alleges that Guidant concealed material information to doctors about the performance of this device.⁷⁴

66. See Dawn House, *Are Guidant Devices a Help or a Hazard*, SALT LAKE TRIB., Nov. 6, 2005, at E1.

67. *Id.*

68. Press Release, Office of N.Y. State Attorney Gen. Eliot Spitzer, Medical Device Maker Sued for Hiding Defibrillator Defect (Nov. 3, 2003), http://www.oag.state.ny.us/press/2005/nov/nov03a_05.html (explaining that the lawsuit alleged that Guidant sold defibrillators with a known design flaw without notifying doctors of the defect, possibly resulting in at least 28 failures of the product and one patient’s death).

69. *Id.* (“Concealment of negative facts that might influence a consumer to purchase another manufacturer’s product is the essence of fraud[.]”).

70. *Id.*

71. N.Y. EXECUTIVE LAW § 63(12) (McKinney 2002).

72. Complaint at 9, *Spitzer v. Guidant*, No. 403656/05 (N.Y. Sup. Ct. filed Nov. 2, 2005).

73. 37 AM. JUR. 2D *Fraud and Deceit* § 1 (2001).

74. Complaint, *supra* note 72, at 2.

III. PHYSICIANS TURN TO MEDIA
—NOT THE FDA—TO ALERT THE PUBLIC

The story about faulty medical heart devices was first made public after twenty-one-year-old college student Joshua Oukrop, died of a heart attack while bicycling in Moab, Utah.⁷⁵ A Guidant official informed Oukrop's cardiologist, Dr. Barry Maron, that the patient's defibrillator had short-circuited and become permanently disabled.⁷⁶ Dr. Maron then contacted a senior consulting cardiologist at the Minneapolis Heart Institute Foundation, Dr. Robert Hauser.⁷⁷ Dr. Hauser searched Manufacturer and User Facility Device Experience (MAUDE),⁷⁸ and found "other reports from Guidant of instances in which the Prizm 2 DR Model 1861 had short-circuited in exactly the same way as Oukrop's had done."⁷⁹ Two months after Oukrop's death, Guidant officials met with Dr. Maron at the Minneapolis Heart Institute.⁸⁰ When Dr. Maron asked how the defect information would be relayed to other physicians and patients, a representative answered that they did not believe they needed to relay the information, nor did they think it was advisable.⁸¹

Maron picked up the telephone and called the *New York Times*.⁸² Dr. Maron never thought to call the FDA because "[i]t is not an agency that has an effective system for this type of issue or the resources to deal with such a problem rapidly."⁸³

After the story broke, Public Citizen, a consumer organization with 135,000 members, petitioned the FDA to establish tighter regulations governing how the FDA evaluates medical devices.⁸⁴

75. See Steinbrook, *supra* note 31, at 221.

76. See *id.*

77. *Id.*

78. See FDA, Manufacturer and User Facility Device Experience Database (MAUDE), <http://www.fda.gov/cdrh/maude.html> (last visited Feb. 5, 2006).

79. Steinbrook, *supra* note 31, at 221, 223 ("As of June 17, 2005, Guidant and the FDA were aware of 43 reports of device failures, including 28 involving Prizm 2 DR devices.").

80. *Id.* at 221–22.

81. *Id.* at 222.

82. House, *supra* note 66.

83. *Id.*

84. Letter from Rachel Roisman, MD, Research Assoc. & Peter Lurie, MD, MPH, Deputy Dir., Pub. Citizen, to Daniel Schultz, MD, Dir., Ctr. For Devices and Radiological Health, FDA (Sept. 14, 2005), available at <http://www.citizen.org/publications/release.cfm?ID=7401&secID=1163&catID=126>.

The system currently allows companies to delay removal of a flawed device while physicians continue to use the remaining inventory.⁸⁵ This practice benefits the manufacturer, which can deplete its inventory of older, defective devices, but endangers patients who receive these inferior products.⁸⁶ In the petition, the group pointed to an example to demonstrate this practice.⁸⁷ One heart-device patient had to have a failed St. Jude pacemaker replaced.⁸⁸ At the time the patient received the second St. Jude device, he was not aware that “St. Jude and the FDA had known that the [second] pacemaker . . . was inferior to another St. Jude device” on the market.⁸⁹

Guidant defended the manufacturer’s performance in a letter to patients:

We at Guidant Cardiac Rhythm Management recognize that our recent *voluntary* physician communications involving several of our pacemaker and defibrillator products may have created concern for you or your family.

All of us at Guidant are deeply aware of the enormous responsibilities that come along with providing products that hold the promise of powerful and positive impact on people’s lives. . . .

. . . .

Presently, we are working with physicians, with outside experts, and with the Food and Drug Administration (FDA) to make even better information available to you and your doctor about product reliability performance.

Importantly, tens of thousands of people are alive and hundreds of thousands of people feel better because of pacemakers and defibrillators. As Guidant, we will continue to work hard to earn your trust.⁹⁰

The FDA released a study in September 2005, which indicated that the number of defective defibrillators increased between the

85. *Id.*

86. *Id.*

87. *See id.* (discussing the case history of one patient, Mark Gleeson).

88. *Id.*

89. *Id.*

90. Letter from Fred McCoy, President, Cardiac Rhythm Mgmt., Guidant, to Patients and Families (Aug. 12, 2005), *available at* <http://www.guidant.com/patient/communication/mccoy.pdf> (emphasis added).

years 1990 and 2002.⁹¹ The study revealed that the defective defibrillators led to thirty-one deaths.⁹² By contrast, the rate of replacing malfunctioning pacemakers steadily declined.⁹³

These figures are likely to be low estimates because the study tracked only surgically removed devices, and doctors are not required to report malfunctions if the patient died from underlying heart disease, which is sometimes a difficult distinction.⁹⁴ In discussing this study, the FDA responded:

All sophisticated medical devices like these have certain risks. Our challenge remains to uncover these risks, measure them, and make information available to patients and doctors to help guide their personalized decisions about where the benefits of technologies like these outweigh known or potential risks from their use.⁹⁵

Gaps in the nation's reporting system are not a new phenomenon.⁹⁶ A 1986 report by the General Accounting Office (GAO), the accounting arm of Congress, demonstrated that doctors reported to the FDA less than one percent of the device problems occurring in hospitals.⁹⁷ The report showed that the more serious the problem, the less likely doctors were to report it.⁹⁸ In a follow-up study three years later, the GAO concluded that reporting problems still existed and that the FDA could have better systems in place to enforce medical device reporting regulation.⁹⁹ A similar study

91. Press Release, FDA, FDA Releases Results of Study on Defibrillator and Pacemaker Malfunctions Part of Agency Drive to Improve Device Safety Monitoring and Public Communications (Sept. 16, 2005), <http://www.fda.gov/bbs/topics/NEWS/2005/NEW01231.html>; see also Neergaard, *supra* note 3 (reporting details of the FDA study).

92. Neergaard, *supra* note 3.

93. *Id.*

94. *Id.*

95. FDA, *supra* note 91.

96. See *supra* notes 89–91 and accompanying text.

97. U.S. GEN. ACCOUNTING OFFICE, GAO/PEMD-87-1, MEDICAL DEVICES: EARLY WARNING OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING 41 (1986), available at <http://archive.gao.gov/f0102/132008.pdf>.

98. *Id.* at 45.

99. U.S. GEN. ACCOUNTING OFFICE, GAO/PEMD-89-1, MEDICAL DEVICES: FDA'S IMPLEMENTATION OF THE MEDICAL DEVICE REPORTING REGULATION 63–66 (1989), available at <http://archive.gao.gov/t2pbat15/138212.pdf>; see also U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-97-21,

released eight years later found that the FDA's reporting system was so slow that the agency was not providing early warnings to the public on device malfunctions.¹⁰⁰ Patients can log onto the FDA's Web site to search the agency's online database MAUDE for information about medical devices.¹⁰¹ Manufacturers themselves, however, provide most of the data,¹⁰² and thus it seems the FDA "entrusts the heart device industry to police itself."¹⁰³

IV. LAWSUIT ABUSE AWARENESS WEEK

Two days after Loyola Law School's symposium, *Access to Justice: The Economics of Civil Justice*, Representative Tom Price of Georgia acknowledged Lawsuit Abuse Awareness Week in front of the U.S. House of Representatives.¹⁰⁴ This recognition reflects the federal government's bias in considering more legislation to curb people's ability to go to court in a variety of areas.¹⁰⁵ The Alliance for Justice, the Center for Justice & Democracy, the Consumer Federation of America, and ten other organizations wrote a letter to the House, stating, "'Lawsuit Abuse Awareness Week' is another in a long line of efforts to shield powerful special interests from accountability for their misconduct."¹⁰⁶ The letter continued: "We urge [Congress] to oppose these bills, and any legislation that protects corporations from taking responsibility for the harms they cause."¹⁰⁷

The appeal was fruitless. In October, 2005, the House passed

MEDICAL DEVICE REPORTING: IMPROVEMENTS NEEDED IN FDA'S SYSTEM FOR MONITORING PROBLEMS WITH APPROVED DEVICES 6 (1997), *available at* <http://www.gao.gov/archive/1997/he97021.pdf> [hereinafter GAO, MEDICAL DEVICE REPORTING] ("[T]he problem still existed despite full-scale implementation of the medical device reporting regulation.").

100. GAO, MEDICAL DEVICE REPORTING, *supra* note 99, at 2.

101. *See* FDA, *supra* note 78.

102. *See id.*; *see generally* GAO, MEDICAL DEVICE REPORTING, *supra* note 99 (describing the FDA's creation of and expectations of the reporting system).

103. House, *supra* note 66; *see* GAO, MEDICAL DEVICE REPORTING, *supra* note 99.

104. *See* 151 CONG. REC. H8252 (daily ed. Sept. 22, 2005) (statement of Rep. Price).

105. *See* Letter from Alliance for Justice et al. to House Representatives (Oct. 18, 2005) (on file with author), *available at* <http://www.centerjd.org/press/release/051018.pdf>.

106. *Id.*

107. *Id.*

the Protection of Lawful Commerce in Arms Act,¹⁰⁸ “which prohibits liability actions against firearms or ammunition manufacturers and sellers for unlawful misuse of their products.”¹⁰⁹ President Bush signed the measure into law on October 26, 2005.¹¹⁰ The House also passed the Personal Responsibility of Food Consumption Act,¹¹¹ dubbed the “cheeseburger bill,” which bans lawsuits against food processors and restaurants concerning food-related health problems and obesity.¹¹² The House additionally passed the Lawsuit Abuse Reduction Act,¹¹³ which would “roll back Rule 11 of the Federal Rules of Civil Procedure to an earlier 1983 version of the rule.”¹¹⁴ These latter two measures must now go before the Senate.

More to the point for patients with defective medical heart devices, the Republican-controlled House passed the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2005 in July 2005,¹¹⁵ which preempts state law on some aspects of medical malpractice liability.¹¹⁶ The measure places a \$250,000 cap on non-economic damages in states that have no limits,¹¹⁷ eliminates joint

108. Protection of Lawful Commerce in Arms Act, 15 U.S.C. A. § 7901 (2005).

109. Press Release, Office of the Press Sec’y, The White House, Statement on S. 397, the “Protection of Lawful Commerce in Arms Act” (Oct. 26, 2005), <http://whitehouse.gov/news/releases/2005/10/print/20051026-1.html>.

110. *Id.*

111. Personal Responsibility in Food Consumption Act of 2005, H.R. 554, 109th Cong. (1st Sess. 2005).

112. *House Passes ‘Cheeseburger Bill’*, CBS NEWS, Mar. 10, 2004, <http://www.cbsnews.com/stories/2004/03/10/health/main605157.shtml>.

113. Lawsuit Abuse Reduction Act of 2005, H.R. 420, 109th Cong.

114. Letter from Alliance for Justice et al. to House Representatives, *supra* note 105; *see also Lawsuit Abuse Reduction Act Opposed by ABA*, Your A.B.A. (A.B.A., Chicago, Ill.), Oct. 2005, <http://www.abanet.org/media/youraba/200510/article09.html> (listing various consequences of the Act, including how “it would impose mandatory sanctions for any violation of Rule 11, removing current safe harbor provisions”).

115. Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2005, H.R. 5, 109th Cong.

116. *See id.* § 11(b); HENRY COHEN, LIBRARY OF CONG., MEDICAL MALPRACTICE LIABILITY REFORM: H.R. 534, 109TH CONGRESS 1–2 (2005), available at <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS2205403072005.pdf> (explaining that state law governs medical malpractice suits but Congress can legislate on medical malpractice suits under the Commerce Clause if the suits affect interstate commerce).

117. H.R. 5 § 4(b); *see also* COHEN, *supra* note 116, at 2 (addressing the effects of H.R. 534, which proposes substantively identical measures as H.R.

and several liability,¹¹⁸ and modifies the collateral source rule.¹¹⁹ In medical malpractice cases, the measure further limits lawyers' contingent fees based on a sliding scale.¹²⁰

The measure, endorsed by Bush,¹²¹ now goes before the Senate.¹²² The night the House passed the liability reform measure, President Bush issued a press release stating:

The Nation's medical liability system is badly broken, as frivolous lawsuits are threatening access to quality health care and raising health care costs for all Americans. The medical liability crisis is driving up health care costs through higher insurance premiums, higher medical bills, and the practice of defensive medicine. . . . This is a national problem that deserves a national solution.¹²³

These are strong words from someone who had been ambivalent about tort reform until John Edwards, former Democratic Senator from North Carolina and trial lawyer, announced in 2003 that he would run for president.¹²⁴

5).

118. H.R. 5 § 4(d); *see also* COHEN, *supra* note 116, at 3–4 (addressing the effects of H.R. 534, which proposes substantively identical measures as H.R. 5).

119. H.R. 5 § 6; *see also* COHEN, *supra* note 116, at 4 (addressing the effects of H.R. 534, which proposes substantively identical measures as H.R. 5).

120. H.R. 5 § 5(a) (stating that 40% of the first \$50,000 the plaintiff recovered, 33.3% of the next \$50,000, 25% of the next \$500,000 and 15% of any amounts exceeding \$600,000); *see also* COHEN, *supra* note 116, at 4–5 (addressing the effects of H.R. 534, which proposes identical measures as H.R. 5).

121. *See* Press Release, Office of the Press Sec'y, President Pleased by House Passage of Medical Liability Reform (July 28, 2005), <http://www.whitehouse.gov/news/releases/2005/07/20050728-7.html> (stating that President Bush was pleased that the House of Representatives continues to pass meaningful medical liability reform legislation and hopes that the Senate will do so in the future).

122. GovTrack, H.R. 5: Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2005, <http://www.govtrack.us/congress/bill.xpd?bill=h109-5> (last visited Dec. 28, 2005).

123. Office of the Press Sec'y, *supra* note 121.

124. Center for Responsive Politics, Health: Medical Malpractice Reform, <http://www.opensecrets.org/payback/issue.asp?issueid=MM2&congrno=108> (hereinafter Health: Medical Malpractice Reform) (last visited Feb. 18, 2006). *But see* Center for Responsive Politics, *supra* note 16 (stating that Republicans and their business allies have *spent years* trying to revise class-action reform lawsuits).

The House passed a similar medical malpractice measure during the 108th Congress that placed caps on non-economic and punitive damages awards¹²⁵ and reduced the statute of limitations.¹²⁶ The Senate struck down a similar bill after Senate Democrats threatened a filibuster.¹²⁷ Republican Senator John Ensign from Nevada who sponsored the bill in the Senate received more than \$300,000 in individual and PAC donations from health professionals, including doctors, who were Ensign's top contributors during the 1997–2002 Senate election cycle.¹²⁸

The American Medical Association (AMA), one of the nation's top political donors and represents doctors nationwide, designated liability reform as its number one issue during the 108th session of Congress.¹²⁹ The AMA contributed \$2.7 million during the 2002 election cycle, earmarking sixty percent of those funds for Republicans.¹³⁰ Conversely, the Association of Trial Lawyers of America, which runs one of the largest PACs in the country, contributed \$3.7 million in individual, PAC, and soft money donations during the 2002 election cycle, giving nearly ninety percent of those contributions to Democrats.¹³¹

Although medical device manufacturers face the same types of product liability claims as any other company, the medical malpractice reform movement may be broad enough to encompass products used in the medical field.¹³² Yet reports stretching back to the 1970s show there are few medical malpractice lawsuits despite an epidemic of medical malpractice.¹³³ “There are [generally] between seven and twenty-five serious medical malpractice injuries for every one medical malpractice lawsuit.”¹³⁴ Tort reform legislation enacted

125. H.R. 5 §§ 4(b)–(c), 7(b)(2).

126. *Id.* § 3 (requiring healthcare lawsuits to commence three years after the date injury manifests or one year after discovery or possible reasonable discovery); *see also* Health: Medical Malpractice Reform, *supra* note 124 (stating that the House bill restricted damages for pain and suffering at \$250,000 and limited the amount of time for a plaintiff to file a lawsuit).

127. Health: Medical Malpractice Reform, *supra* note 124.

128. *Id.*

129. *Id.*

130. *Id.*

131. *Id.*

132. TOM BAKER, THE MEDICAL MALPRACTICE MYTH 11 (2005).

133. *Id.* at 2.

134. *Id.* at 23.

since 2000 in many states nonetheless suggests that legislators and voters believe medical malpractice lawsuits threatened health care more than medical malpractice.¹³⁵

Indeed, a poll leading up to Lawsuit Abuse Awareness week released by SickofLawsuits.org showed “seventy-nine percent of Americans believe advertising by personal injury lawyers encourages people to sue even if they have not been injured.”¹³⁶ A spokesperson for the Sick of Lawsuits campaign explained:

Generally speaking, frivolous lawsuits and outrageous jury awards threaten our access to affordable health care, reduce medical innovation and take life-saving medicines off the shelves. Patients who have been harmed deserve fair compensation that has not been diluted or delayed by some greedy personal injury lawyers and uninjured patients looking to cash in.¹³⁷

Back in Salt Lake City, Zina Lewis is diligently working away, trying to gather what she says is life-saving information from Guidant and the FDA.¹³⁸ She needs this information to help her make decisions regarding more surgeries on her pacemaker and its lead wires on which she is totally dependent to keep her heart beating.¹³⁹ Besides writing repeatedly to Guidant and the FDA, she also appealed to more than twenty members of Congress, including her Republican senator from Utah, Orrin Hatch, and Health and Human Services Secretary Mike Leavitt, a former Utah governor and family acquaintance.¹⁴⁰ Senator Hatch replied to Lewis’s letter, “expressing his concerns and touting the Medical Device User Fee

135. *Id.*

136. Press Release, Sick of Lawsuits, SickofLawsuits.org’s National Education Campaign Reveals Americans’ Concerns about Personal Injury Lawsuit Advertising (Sept. 19, 2005), http://www.sickoflawsuits.org/content/news/media_20050919.cfm (stating that a national survey of 800 likely voters was conducted by Public Opinion Strategies on behalf of Citizens Against Lawsuit Abuse—a nonpartisan, grassroots campaign representing more than 165,000 supporters, including doctors, healthcare providers, small business owners and attorneys).

137. E-mail from Evelyn Tobias-Merrill, Spokesperson, Sick of Lawsuits, to Dawn House, Reporter, The Salt Lake Tribune (Nov. 30, 2005, 08:30:00 a.m. MST) (on file with author).

138. See House, *supra* note 41.

139. *Id.*

140. *Id.*

and Modernization Act that allows inspections of certain device manufacturers.”¹⁴¹ Company participation in this program is, however, voluntary.¹⁴²

Earlier in September 2005, Lewis traveled to Washington D.C. to speak at the national conference hosted by the Heart Rhythm Society and the Heart Rhythm Foundation in cooperation with the FDA.¹⁴³ She was the only speaker not connected to a heart-device manufacturer, government organization, or media source to speak at the conference.¹⁴⁴ During the question and answer portion of the conference, the moderator cut Lewis off before she could ask two questions of federal regulatory officials and manufacturers:¹⁴⁵ How much information is withheld from the public because it is considered a corporate trade secret?¹⁴⁶ And, without full disclosure, how can physicians practice evidence-based medicine?¹⁴⁷

Shortly before Lewis’ surgery in November 2005 to replace her defective Insignia model, Lewis unsuccessfully attempted to obtain more information from Guidant on whether the lead wires that connect the device to her heart should be replaced.¹⁴⁸ Explaining the importance of obtaining the information about her heart devices, Lewis said:

Despite the rash of recalls and safety concerns, many of us have been deliberately denied access to safety data on devices, which we currently have implanted. This industry begs for litigation by its betrayal of patient safety and disclosure and indifference to human suffering, not because of fallibility of products or human error. . . . The obligation is unique to this industry among all others, because every

141. *Id.*

142. *Id.*

143. LEWIS, *supra* note 38, at 2.

144. *Id.* at 1 (Speaking at the conference were: Mike Leavitt, Secretary of Health and Human Services; Senator Chuck Grassley, Chairman, Committee on Finance; Dr. Robert J. Myerburg, Chair, Guidant Independent Panel; Barry Meier, The New York Times; and Zina Lewis, MS, SPRN-C, CRRN, Director, Steward Development).

145. E-mail from Zina Lewis to Dawn House, *supra* note 34.

146. *See* LEWIS, *supra* note 38, at 4 (listing this question in Lewis’ abstract as part of Lewis’ prepared speech for the conference).

147. *See id.* (listing this question in Lewis’ abstract as part of Lewis’ prepared speech for the conference).

148. House, *supra* note 41.

action (or inaction) can affect a patient's life—and a family who grieves when one is permanently disabled or dies. The implications are potentially catastrophic. This recent corporate behavior has made many of us feel like “ticking time bombs.”¹⁴⁹

About the same time as Lewis' surgery, the manufacturer was under scrutiny by federal investigators, and a \$25 billion deal to be acquired by Johnson & Johnson appeared shaky.¹⁵⁰ Guidant disclosed that “failure of lead wires is substantially more common than that of the device itself.”¹⁵¹ The manufacturer “cited 109 cases involving one lead-wire model, and 70 cases involving another.”¹⁵² By contrast, the majority “of Guidant defibrillators have experienced fewer than five device failures during their lifetimes.”¹⁵³ A cardiologist at Virginia Commonwealth University said that “[d]efibrillators ‘are 99%-plus reliable . . . But leads are less reliable, and in five to 10 years maybe 3 % to 5 % of leads will have to be replaced.’”¹⁵⁴

In November 2005, Guidant and Johnson & Johnson entered into a revised agreement in which Johnson & Johnson acquired the manufacturer for \$21.5 billion.¹⁵⁵ The companies, which originally entered into an acquisition agreement in December 2004, expect to close the deal in the first quarter of 2006.¹⁵⁶ When questioned about the agreement, the chairman of Guidant said, “Our enthusiasm for this agreement and its potential continues. This agreement makes sense for Guidant shareholders and employees. It amplifies the opportunity for us to do more for patients with cardiovascular disease through a union with Johnson & Johnson.”¹⁵⁷

In December 2005, however, Boston Scientific Corporation

149. LEWIS, *supra* note 38, at 3–4.

150. Thomas M. Burton, *Guidant Finds Wires Are Cause of Most Defibrillator Failures*, WALL ST. J., Nov. 10, 2005, at D6.

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

155. Press Release, Johnson & Johnson, Johnson & Johnson and Guidant Corporation Announce Revised Acquisition Agreement with Net Value of \$19 Billion (Nov. 15, 2005), http://www.jnj.com/news/jnj_news/20051115_064824.htm.

156. *Id.*

157. *Id.*

made an unexpected \$25 billion takeover offer for Guidant, bidding more than \$3 billion more than what Johnson & Johnson had agreed to pay the month before.¹⁵⁸ The newest offer came nearly a year after Johnson & Johnson said it would buy Guidant for \$25.4 billion.¹⁵⁹ Johnson & Johnson had cut that price by nearly \$4 billion after the series of product recalls.¹⁶⁰

Boston Scientific won the bidding war in late January 2006, agreeing to pay a final price of \$27 billion for Guidant.¹⁶¹ That same month, the FDA warned Boston Scientific that the government had concerns about quality control in Boston Scientific's own factories and its medical devices' safety.¹⁶² FDA officials said the timing of their warning was coincidental with the merger deal, but they also suggested that the problems had festered, in part, because top executives (who had spent nearly two months in the bidding war) had failed to resolve the safety issues.¹⁶³ The FDA did not, however, order product recalls, and placed no restrictions on the company's ability to sell its devices.¹⁶⁴

V. CONCLUSION

The marketplace initially seemed to penalize Guidant's belated release of data until Boston Scientific opened up a bidding war. Both the Republican-controlled Congress and health-care providers have heated up their rhetoric in limiting people's ability to go to court as a cure-all to rising medical costs. Also, while Congress has passed or is considering tort reform, lawmakers are not examining whether corporate trade secrets should be curbed so that data can be released on heart products' failure rates, or if regulatory agencies are protecting the public's health.

158. Ken Kusmer, *Guidant Draws \$25B Bid from Rival: Boston Scientific tops Johnson & Johnson's offer by \$3B*, N. COUNTY TIMES, Dec. 6, 2005, at D1 available at <http://www.nctimes.com/articles/2005/12/06/business/news/12505190745.prt>.

159. *See id.*

160. *See id.* (stating that Guidant and Johnson & Johnson's original deal stalled after a series of product recalls and regulatory investigations).

161. Gardiner Harris & Barnaby J. Feder, *FDA Warns Device Maker Over Safety*, N.Y. TIMES, Jan. 27, 2006, at C1, available at <http://www.nytimes.com/2006/01/27/politics/27device.html>.

162. *Id.*

163. *Id.*

164. *Id.*

Zina Lewis and other patients who have vital information gleaned from painful, personal experience have gone missing from the debate. The absence of their voices may exact a heavy price because heart disease is the nation's number one killer.¹⁶⁵ Statistics show that sometime during our lifetimes we, or our loved ones, could become dependent on a heart device.¹⁶⁶

165. AM. HEART ASS'N, HEART DISEASE AND STROKES STATISTICS—2006 UPDATE 7 (2006), *available at* <http://www.americanheart.org/downloadable/heart/1136308648540Statupdate2006.pdf> (reporting that in 2003 cardiovascular disease accounts for every 2.7 deaths in the United States and claims nearly one life every 35 seconds).

166. *See id.* at 6–7.